REMARKS

Claims 1-106, 108-110, 112 and 114 are canceled, claims 107, 111, 115, 116, 118 and 119 have been amended, and new claims 120 and 121 have been added. Claims 107, 111, 113 and 115-121 are now pending for the Examiner's consideration.

Claims 107, 111, 115, 116, 118 and 119 have been amended to delete "about". New independent claim 120 rewrites claim 113 in independent form, and new dependant claim 121 recites preferred concentration ranges. No new matter is added.

Applicant respectfully requests favorable consideration of the pending claims.

Applicant thanks the Examiner for the courtesy extended during a personal interview with attorney Jeffrey H. Tidwell on June 22, 2009. Applicant agrees with the Examiner's Interview Summary Form mailed June 30, 2009, and further provides the following brief summary of the interview. Attorney Tidwell and Examiner Schlientz discussed claims 107, 111, 113 and 115-119 and the Shenoy reference. As noted in the Interview Summary, attorney Tidwell pointed out numerous instances of selections that would need to be made from the Shenoy reference in order to choose the claimed invention, including the active agent, the salt, the amount of each agent in the dosage form, the specific dosage form and the types of formulating components, for example. Attorney Tidwell further argued that Shenoy exemplifies oil suspensions and teaches that such oil suspensions have higher bioavailability than a wet granulated tablet, thus teaching away from the presently claim solid dosage forms. Attorney Tidwell argued that the picking and choosing required, and the teaching away from solid dosage forms, make the present claims non-obvious over Shenoy.

In the Office Action dated March 4, 2009, claims 107, 111, 113 and 115-119 were rejected under 35 U.S.C. § 112, second paragraph, for the reasons set forth on page 3 of the Office Action. These claims and/or those they depend from have been amended to delete the term "about". Applicant believes the rejection has been overcome, and request that it be withdrawn.

Claims 107, 111, 113 and 115-119 were rejected under 35 U.S.C. § 103(a) as being unpatentable over International Application Publication WO 01/37820 ("Shenoy"), in view of U.S. Patent No. 4,609,675 ("Franz") and U.S. Patent No. 6,077,533 ("Oshlack") for the reasons set forth on pages 4-9 of the Office Action. Applicant respectfully traverses.

As noted in the June 22, 2009 interview, one must make numerous selections from the disclosure of Shenoy to arrive at the presently claimed invention, and it would not have been obvious to make such selections. Some of the selections include:

(1) Active agent: Shenoy discloses at least 260 compounds, with the preferred compound having a carboxylic acid moiety (propionic acid) on the pyrrole ring. The present claims include a compound having a diethylaminoethyl amide group on the pyrrole ring. There is no suggestion that would lead one of ordinary skill in the art to select the claimed compound, having a basic terminal group ($-N(Et)_2$), from the several hundred disclosed compounds having various functionalities, particularly in light of the preference for the propionic acid compound.

(2) L-malate salt: Shenoy does not teach the malate salt of the present compound, but only lists various salts as possibilities for the disclosed compounds in general. Even if one were to select the presently claimed compound from the several hundred compounds disclosed in Shenoy, there is no teaching or suggestion that would direct one of ordinary skill in the art to choose the L-malate salt. Thus, at least a second selection must be made to arrive at the presently claimed invention.

(3) Solid formulation: Shenoy teaches various formulation types, and exemplifies parenteral formulations and oil suspensions in addition to solid formulations. Example 5 (page 229-231) of Shenoy compares the oral bioavailability of an oil-suspension formulation to that of a conventional wet granulated tablet, and shows that the oil-suspension provides a mean AUC of from three to four times that of the tablet, showing greater bioavailability. Clearly high bioavailability is desirable, and one of ordinary skill in the art would reasonably conclude from the Shenoy teaching that oil suspensions are preferred. Despite this apparent superiority of oil suspension dosage forms, one of ordinary skill in the art would need to choose instead a solid dosage form. Thus, at least a third selection must be made to arrive at the presently claimed invention, and Shenoy appears to teach away from this selection.

(4) Specific component amounts: As noted previously, Shenoy discloses an extremely broad range of concentrations for each of many possible components. In the table on page 96, for example, Shenoy discloses 5-90% active ingredient, with a "most preferred" range that is unhelpfully nearly as broad, 15-75%. This range is so broad as to be useless in guiding one of ordinary skill in the art to the narrow ranges recited in the present claims.

Further, as applicants have noted, the wrong choices give rise to inferior properties, such as poor bulk densities or sticking problems. Thus, in addition to the many choices already outlined, one of ordinary skill in the art must make further choices in the amount of active ingredient and the specific components and amounts of such components to arrive at the presently claimed invention.

In light of the multitude of selections required from the broad disclosure of the Shenoy reference, Applicant believes the present claims would not have been obvious over Shenoy alone or in view of Franz and Oshlack. Neither Franz nor Oshlack provides guidance to select the presently claimed active ingredient or the L-malate salt thereof, or the specifically claimed narrow concentration references. Both Franz and Oshlack are directed to formulations of compounds chemically unrelated to the compound in the present claims. At most, Franz and Oshlack support the proposition that a high bulk density is desirable, but they do not cure the deficiencies of Shenoy in making the many selections needed to attain such bulk densities in solid dosage forms of the presently claimed compound.

Accordingly, Applicants believe the present claims would not have been obvious over Shenoy in view of Franz and Oshlack, and request that the rejection under §103 be withdrawn as to all the pending claims.

With specific reference to claim 113 (and new claims 120 and 121), which recites that the composition does not comprise a flow enhancer or surfactant, Applicants point out that when Shenoy does choose to exemplify a solid formulation, as shown in Table 11 on page 233, Shenoy shows that with a 28% concentration of active ingredient, all of the exemplified formulations include 0.5% colloidal silicon dioxide, a flow enhancer, and either sodium lauryl sulfate or cetylpyridinium chloride as surfactants. In the Table on page 96 (bottom) that the Examiner relies on to show the broad ranges of components such as 15-75% active ingredient, both the "preferred" and "most preferred" formulations include at least 0.3% flow enhancer and at least 0.1% surfactant. Further, as shown in the Comparative Example of the present specification, Table 1, a composition having 75% active ingredient shows sticking problems, also suggesting the need for flow enhancer. Thus, it would not have been obvious at the time of the invention to prepare the formulation of claims 113, 120 and 121, having an active ingredient concentration higher than that of Shenoy's 28%, but without including a flow enhancer or surfactant.

Accordingly, as to claim 113 specifically, Applicant respectfully requests that the rejection under §103(a) over Shenoy in view of Franz and Oshlack be withdrawn.

The corresponding patent application in Europe has granted as EP 1 536 783 B1, and an opposition has been filed against the EP patent. Applicant is filing concurrently herewith (filed via Express Mail) a Supplemental IDS with the Opposition Brief filed by the opponent and copies of the cited art.

Applicant believes all claims are now in condition for allowance. Should there be any issues that have not been addressed to the Examiners satisfaction, Applicant invites the Examiner to contact the undersigned attorney.

If any fees other than those submitted herewith are due in connection with this response, including the fee for any required extension of time (for which Applicant hereby petitions), please charge such fees to Deposit Account No. 161445.

Respectfully submitted,

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